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(54) Title: METHOD AND APPARATUS FOR A CONTROLLED CUSTOMISATION OF THE CORNEA

(57) Abstract: The present invention covers a method and apparatus to measure the position of an eye in up to 6 degrees of freedom, the pupil diameter and the identity of an eye in different diagnosis and treatment instruments and to link and relate the different positions measured at different times and/ or in different instruments to each other. The method used for linking and relating the position measurements to each other is a co-ordinate transformation between the different system co-ordinate systems and the eye co-ordinate system as measured by image processing or other measurement techniques to obtain either single or combined measures of degrees of freedom. In addition to the position of the eye, the identity of the eye under diagnosis or treatment can be measured and recognized in the different instruments and systems. The measurement of the eye position and pupil diameter can also be done with different measurement techniques like standard or non-standard video image analysis from one or several cameras per system, optical coherence tomography, laser interferometry or others.

TITLE

Method and apparatus for a controlled customisation of the cornea

Background of the Invention

The present invention is directed to improve methods of ophthalmic diagnostics and / or ophthalmic treatment processes and apparatuses implementing such methods. The technique according to the present invention improves the accuracy of diagnosis, comparing or synthesising diagnoses from different devices and/or for performing treatments or corrections based on these diagnoses. The applications relevant to the present invention include refractive surgery of the cornea, (PRK, LASIK or LTK), insertion of prosthetic devices such as intraocular lenses (IOLs) or retinal chips and other corrective surgery such as retinal surgery or glaucoma surgery.

Ophthalmic diagnostics require that the optical, spatial, visual or physical characteristics are determined. Visual or refractive performance is measured with auto-refractors, perimeters, corneal topographers or more recently with wave front aberrometry techniques providing information also of higher orders of aberrations of the eye (two dimensional optical characteristics). Topometry / topography systems provide a 2 dimensional elevation map of the shape of the cornea, which has a major influence on the refractive performance of the eye. Spatial characteristics include corneal pachymetry, lens thickness or position, anterior chamber depth, axial length and retinal thickness. The characteristics may be measured with ultrasound, optical coherence tomography, confocal microscopy, video image processing or other optical techniques. Physical characteristics include optical disk size, blood vessel density or features on the retina such as cotton wool spots and these may be measured using a camera, microscope or ophthalmoscope and image processing techniques. For one patient, a variety of instruments may be used to measure different characteristics of the eye, and each of the measurements will be done at different periods of time. A comparison or synthesis of these measurements may be needed to make a diagnosis and the spatial registration may be critical to the overall accuracy.

The treatment that arises from the diagnosis may also be spatially dependent, wherein the efficacy of the treatment depends on where it is placed on the eye. Therefore, the treatment

must also be registered on the patient's eye. For example, the positioning of an ablation profile for laser vision correction or laser thermal keratoplasty (LTK), the positioning of an intra-ocular lens (IOL) for refractive correction or other prosthetic device such as retinal implant or artificial cornea, or the positioning of a laser beam for vitrectomy, retinal reattachment or other retinal surgery or for glaucoma surgery. The treatment may be performed using a surgical instrument different to the diagnostic instrument; such as a refractive laser device, microscope, vitrectomy system or other laser delivery system.

The two most common applications where the present invention could be applied are laser refractive surgery and intra-ocular lens implantation.

With the refractive laser surgery technique, the shape of the cornea is altered in a way that the optical deficiencies of the whole eye are compensated. Using a x-y scanner to control the position of the laser contact point on the eye or cornea, complex ablation profiles can be applied to correct for non-spherical optical characteristics (i.e. astigmatism), higher order of aberrations or even perform prismatic corrections on both eyes to adjust vergence / strabism.

As shown in figure 1, with a pre-surgery diagnosis the actual shape of the cornea and its optical characteristics are determined. Using modelling (comparing actual and ideal corneal surface) and knowledge about the laser ablation process an individual customized ablation profile can be computed to improve overall vision. During treatment corneal tissue is ablated with a multitude of laser shots according to the ablation profile in order to shape the cornea to its ideal profile. Due to the patient's eye movements during the surgery procedure, eye trackers are commonly used for measurement of the actual eye position and with the use of a positioning device, for example a x-y-scanner for the laser, these eye movements are compensated by correcting the ablation position with the changed eye position. In the future, even online monitoring such as registration of actual laser ablation positions on the eye or online changes of the elevation (Online – Topography) may be used. After laser treatment the corrected corneal shape may be re-examined with the same or other diagnostic techniques as before treatment.

An alternative technique for correcting refractive errors, is the insertion of intra-ocular lenses. The present invention can improve the rotational orientation, tilt and centration of the placement of an artificial lens placed inside the eye. These artificial intra-ocular lenses

(IOLs) are used to either replace the phakic lens in cataract surgery, or to correct refractive errors.

The technique for correcting refractive errors is to implant an artificial lens with a particular form and refractive power to compensate for the measured refractive error of the eye either in front of the lens or iris. The operation is completely reversible and leaves the central area of the cornea intact — two strong advantages over laser refractive surgery.

While the majority of IOL procedures are performed to correct high myopia, astigmatic intra-ocular lenses are also available. These lenses are asymmetric and therefore, the rotational alignment is important for the optimal correction of astigmatism. As with laser refractive surgery, the first step is to measure the refraction spherical error, cylinder and astigmatic axis using an ophthalmic diagnostic device, such as phoropter, corneal topographer, spatial refractor or aberrometer. A suitable lens for the refractive error can either be selected as an off-the-shelf component or manufactured individually for the patient.

Intraocular lenses are also used in the treatment of cataracts. When the lens becomes opacified, it must be removed and replaced with an artificial lens. Approximately 20% of cataract patients have pre-existing astigmatism that could be treated using an asymmetric or toric lens.

Intraocular lens surgery may be combined with laser refractive surgery to make small adjustments to the refractive correction.

The present techniques are limited in accuracy. In a study of 37 eyes, almost 20% of IOLs were rotationally misaligned by 25° (cf. Ruhswurm, Irene. Scholz, Ursula. Zehetmayer, Martin. Et al. "Astigmatism correction with a foldable toric intraocular lens in cataract patients" J Cataract Refract Surg. 2000;26:1022-1027). This rotation alignment can be made simpler and more reliable by the present invention.

The present art of ophthalmic diagnosis and treatment has some deficiencies, thus limiting the overall accuracy and reliability of the whole process:

1. For each step in the process from pre-surgery diagnosis over treatment to post-surgery diagnosis with sometimes multiple diagnostic and treatment techniques involved in each step, an adjustment procedure has to be performed, generally referred to as centration, with the purpose of aligning the patient's eye to the diagnostic or treatment device. This device dependent centration procedure is often based on the human judgement of the surgeon or technician performing the alignment with little objective guidance or control, resulting in poor repeatability and accuracy of measurements, inaccurate treatment computation and inaccurate positioning of the treatment or lens on the eye.

2. Centration errors become even more problematic when eye related data from different devices (for example corneal thickness measurement together with topography) are compared, since here these errors sum up. Furthermore centration often is based on the pupil centre even though it is known that pupil diameter changes have an effect on the position of the pupil centre with respect to the optical axis.

3. Since the treatment changes the characteristics of the eye such as refraction, any centration procedure based on an optical reference axis or the optical system might be biased, resulting in a lack of comparability between pre- and post-surgery diagnosis.

4. If a surgical system does include some form of eye tracking, such as laser ablation systems, only a two-dimensional eye tracking during treatment is used, while the eye is kept within a constant distance to the laser source. However, the eye has in principle 6 degrees of freedom (three translational and three rotational).

5. Slight head movements may also result in a different distance of the eye to the device. This is especially problematic for laser delivery systems, which are focussed with their energy constant only over a limited range. Changes in distance therefore result in changed energy on the eye and therefore uncontrolled surgical effect.

6. The eye also performs eye movements about the line of sight – torsional eye movements (vestibular ocular reflex) and the head position in roll may be different when the patient is supine under the one device and sitting up at another device. This

results in inaccurate positioning of diagnosis or treatment which may not be rotationally symmetric.

7. Furthermore, sometimes the left eye may be treated with the prescription and treatment for ablation profile calculated for a different patient. This unsafe handling of data and missing objective control results in severe mistreatment and possible damage of the patient's eye.

Summary of the Invention

The overall objective of the present invention is to provide a common, eye based reference system for ophthalmic diagnosis and treatment to increase reliability and accuracy as well as to enable an improvement of the overall process and outcome of ophthalmic diagnosis and treatment. A further objective is to improve the registration of different diagnostic techniques, where a combination of measurements is needed to diagnose the eye. A further objective of the invention is to provide the basis for aligning or placing individual, non-spherical refractive corrections of high quality to allow correction for astigmatism, higher order aberrations etc. A further objective is to allow the accurate placement of other ophthalmic surgeries such as retinal treatments or inserting corrective prosthetic devices such as IOLs. Still a further objective of the invention is to increase security of the treatment by ensuring identity of the eyes during different diagnostic and treatment steps.

These goals are achieved by comparison of eye position measurements performed during each diagnosis and/or treatment and then linking the eye related data (such as elevation, aberrations and ablations profiles or lens position) to a common eye fixed reference system. Figures 1 shows the process by which the different coordinate systems are linked.

Co-ordinate transformations for data obtained originally in device coordinate systems into the common eye co-ordinate system are supplied, thus ensuring best possible comparability, reliability and precision. By the integration of eye torsion into the common eye coordinates it is guaranteed, that even non-rotationally-symmetric corrections or prosthetic devices can be placed relative to the eye.

Furthermore, the eye is analysed using pattern recognition techniques, such as iris recognition, in order to provide identification of the eye with each measurement. Before application of any

treatment, this identification is performed to secure that the correct patient and correct eye is treated.

A preferred embodiment for the determinations of eye position and orientation coordinates by using a multi camera system in combination with torsional measurements and eye identification using iris recognition is proposed.

The objectives of the present invention are achieved by providing the doctor with an objective measurement of the eye position relative to the device and orientation of the lens relative to an eye-based coordinate system. These positions are calculated in an eye-based coordinate system, based on the reference image taken in the diagnostic process.

An image of the eye during the diagnostic measurement is saved to a memory device, and the characteristics of the eye such as but not limited to aberration map, topography, astigmatism axis, retinal thickness, optical disk depth, blood vessel density etc. relative to this eye based coordinate system are recorded.

The present invention also makes a quality check of the reference image, to ensure that it can be used as a basis for position comparison at later steps. This check ensures that the features required to fix the coordinate system, or to compare the image with a second image to find a relative transformation, are present in the image.

At subsequent instruments or subsequent diagnosis or treatment, images of the eye can be captured and using image-processing techniques, the position of the eye relative to the eye during the first diagnostic measurement (the original eye-based coordinate system) can be calculated. This displacement can be done in anything up to 6 dimensions (cf. Elander, R., Rich, L.F., Robin, J.B.: "Principles and Practice of Refractive Surgery"; W.B. Saunders Company, Philadelphia; 1st ed.,1997), but in the preferred embodiment at least x, y and torsion around the visual axis. In procedures, where the pupil is a natural size or constricted, naturally occurring iris landmarks can be used to calculate the torsion of the eye around the visual axis. If the eye is dilated and the iris is no longer sufficiently visible, artificial landmarks or markers can be used to calculate the ocular torsion and / or translation. In this way, a transformation is found between the coordinate system of the eye during surgery and the coordinate system of the eye during diagnostics is found.

The invention can also return a confidence level based on the level of correspondence between the reference image and measurement image. This indicates the accuracy of the calculated transformation. Once the transformation has been calculated, either the diagnostic data or treatment data is transformed to ensure a constant coordinate system.

For the embodiment of the invention for IOL surgery, the position of the lens relative to the eye based coordinate system can be also calculated from the surgical image. For example, using the alignment marks on the rim of the optics or the footplates or haptics of the IOLs, the rotational alignment of the lens can be calculated relative to the eye based coordinate system, and hence the astigmatic axis of the eye. Tilt could also be calculated by measuring the distance between these alignment marks or the distortion of the image of the lens relative to the camera. The centration could also be calculated from the alignment marks, or from image processing of the lens.

The image of the eye during surgery can then be displayed to the doctor, for example on a computer monitor, with the actual position of the lens and desired position of the lens overlaid. This provides the feedback to the doctor, who can then adjust the location of the lens towards the desired orientation. The measurement is then repeated to ensure the position is correct. Else the lens is readjusted and the measurement repeated etc.

For the embodiment of retinal surgery, the invention may also give the position on the eye at which the laser beam is aimed as feedback to the clinician.

SHORT DESCRIPTION OF THE DRAWINGS

Fig. 1) state of the art processing scheme

Fig. 2) general processing scheme for determination of coordinate transformation from image transformation

Fig. 3) schematic transformation paths

Fig. 4) schematic three camera system

Fig. 5) embedding of schematic eye in coordinate system

Detailed Description

To overcome the problems mentioned above, this invention provides a common eye-fixed coordinate system and the methods to localize this reference system by determination of all six degrees of freedom of the eye during each pre-/post diagnostic measurement and laser treatment.

As shown in fig. 5, the origin of the eye-fixed co-ordinate system (preferably Cartesian) E is placed into the centre of the eye. Here the xe-ye-plane lies perpendicular to the optical axis of the eye, which itself is aligned with the ze- axis of the eye fixed coordinate system. Whereas ze-axis and origin are well defined, the orientation of the xe- and ye-axis withing the xe-ye plane must still be fixed to the eye. This fixation is done by acquiring an image of the eye to document the eye position with respect to the device fixed reference system. It is appropriate to define the torsion to be equal to zero to the eye position as acquired in the reference image.

This eye fixed reference system is embedded in the 3-dimensional device/system fixed reference system (right-handed Cartesian co-ordinate system) by the position vector X=(x y z) that determines eye translation and by Euler's angles PHI, THETA and PSI, that determine eye rotations with respect to the device/system fixed reference system. Here PSI can be identified with the torsion angle of the eye. PHI and THETA determine the inclination angles of the eye.

With respect to the application in diagnostic or treatment procedure, importance of the eye coordinates differs. Generally, the most important coordinates, however, are the translational coordinates x, y, z, determining the resulting angles under which the centre of the pupil or limbus or fundus occur relative to the optical axis of the camera as well as the distance from eye to the observing device. The angle PSI of the torsional rotation of the eye about its optical axis can also vary significantly between measurements and treatments due to eye and head movements and different positions of the head relative to the instrument(s). The inclination angles PHI and THETA are of minor importance, since they are usually held approximately constant by asking the patient to fixate a marker and to avoid head movements. Nevertheless, for increase accuracy, these angles should also be included.

Linkage between diagnosis and treatment/ co-ordinate transformation

During diagnosis or treatment it is appropriate to address any point P on the eye in a 3-dimensional device/system fixed coordinate system REF with the coordinates R = (x y z). These coordinates do not refer to the same point on the eye anymore, if the eye moved relative to the space-bound reference system. This also holds, if different devices are involved. In this case, the difference between the eye positions relative to the coordinate systems of those devices can be interpreted as an eye movement relative to the same coordinate system. Now, this point P is addressed by the new coordinates R' = (x' y' z'),

depending on the position and orientation of the eye before and after the movement. In eye fixed reference system the equivalent coordinates of point P are constant and given by the vector e =(xe ye ze). As shown in fig. 4, the linkage between the two reference systems is given by the two coordinate transformations

$$e = A^T(R-X) \text{ and } R = Ae + X$$

if X = (x y z) is the position vector for the origin of the eye fixed reference system and PHI, THETA and PSI the underlying rotation angles of the eye. A^T is the transposed matrix of the rotation matrix A, which is given by its elements A_{ij}, with

$$A_{11} = \cos PHI \cos PSI - \sin PHI \cos THETA \sin PSI$$
$$A_{12} = -\cos PHI\ SIN\ PSI - \sin PHI \cos THETA \cos PSI$$
$$A_{13} = \sin PHI\ SIN\ THETA$$

$$A_{21} = \sin PHI \cos PSI + \cos PHI \cos THETA \sin PSI$$
$$A_{22} = -\sin PHI \sin PSI + \cos PHI \cos THETA \cos PSI$$
$$A_{23} = -\cos PHI \sin THETA$$

$$A_{31} = \sin THETA \sin PSI$$
$$A_{32} = \sin THETA \cos PSI$$
$$A_{33} = \cos THETA.$$

Therefore, these transformations provide the linkage between eye related data and the eye position for exchange: eye related data at any point P, addressed for example in a diagnostic device by its position vector R (in system/device fixed coordinates) is addressed by the equivalent position vector e in eye fixed coordinates. The transformation paths are shown in Figure 3.

In order to provide a linkage between different system/device fixed reference systems a combination of the above transformations is used to set up the transformations T and TINV. T and TINV map the position vectors R and R' of different device fixed coordinate systems of the same point on the eye onto each other, as shown in fig. 4. T and TINV can be calculated using the indirect way over the eye fixed coordinates e. The device fixed (System APP) position vector R', due to eye position x', y', z' and eye orientations PHI', THETA' and PSI' is linked to its position vector R (in system REF) with eye position x,y,z and eye orientations PHI, THETA and PSI by the transformations

$$T: R' = A'e + X' = A'A^T(R-X) + X' \text{ and}$$
$$TINV: R = Ae + X = A(A')^T (R'-X')+X$$

Here all prime variables refer to second System APP, but are defined as above. For generality, APP and REF do not have to be different devices: This invention is also applicable to one device with APP and REF referring to different eye positions in the same device at subsequent times or eye positions relative to different camera positions in a more camera system.

As above, eye related data at any point P on the eye is addressed in different systems REF and APP by the equivalent position vectors R and R'. Therefore the transformations T and TINV provide the ability to exchange eye related data between different devices or eye positions, respectively. The important advantage of the eye fixed reference system is that any eye related data given in this system does not rely on the eye position and orientation.

The use of the above mentioned coordinate transformation requires a localization of the eye fixed reference system. Therefore the eye coordinates in system/device fixed reference system have to be determined in order to set up the vectors needed for transformation. If one takes care that any subset of the coordinates remain constant, these transformation will only have to be applied to the remaining subset of coordinates. Fig. 2 shows a possible processing path for localisation of the eye based co-ordinate system by image transformations.

Localization of the eye-bound reference system

In order to localize the eye fixed reference system, the eye position has to be determined for all six degrees of freedom. For localization of the eye fixed reference system in a space- or device-bound reference system, different techniques can be combined:

In the preferred embodiment of the invention a triangulation procedure is used in order to determine the translational coordinates of the eye in the space-bound reference system.

Any triangulation procedure, using more than one camera, can determine the exact position of the eye in three dimensions without the need to perform advanced image evaluation due to geometric distortions etc. Here, all cameras measure individual optical angles, i.e. horizontal and vertical angles between optical axis of the camera and the visual axis under which a prominent spatial characteristic on of the eye occurs. If all camera positions and orientations are known, the spatial coordinates of this prominent spatial characteristic are given by the

intersection of the visual axes of the cameras. For triangulation only two cameras are necessary, as the intersection is already possible for two visual axes. Due to imperfect adjustment of the cameras, a calculation of the intersection point of the visual axes might fail, although the visual axes should intersect. In this case no conclusions can be drawn about the correct camera positions. With a triangulation using more than two cameras, the camera positions and orientations need not be known with great accuracy, because this additional information enables a correction of the camera positions.

In the preferred embodiment, the eye's translational coordinates are measured with a triangulation procedure using up to three cameras for eye tracking as shown in fig. 5. One camera (Camera 1) is positioned in front of the eye in the optical axis of the eye. The others (Camera 2 and 3) are positioned to the left and right of the eye, viewing the eye from below the line of sight. Thus the camera positions form a triangle in front of the eye, with the optical axis intersection preferably at the centre of the eye. Here, the cameras measure the visual angles, i.e. the horizontal and vertical angles between the optical axis of each camera and the visual axis, i.e. the direction under which the origin of the eye fixed reference system occurs. The intersection point of these visual axes is identical with the origin of the eye fixed reference system and therefore the eye's translational coordinates can be calculated, if all positions and orientations of the cameras are known.

With at least three cameras used for triangulation, a detection of misalignment of the cameras is possible. This is not the case for a two-camera system, where a precise determination of the eye's translational coordinates is only possible, if the exact camera positions are known. With the preferred system all six coordinates of the eye could be measured by triangulation of three different points on the eye, e.g. with two further so-called landmarks that can be recognized easily.

With only one prominent point or fixed spatial landmark under observation, the coordinates x, y, z in the space-bound reference system can be determined.

In another embodiment, only one camera is used for calculating x and y translational coordinates, wherein a fixed landmark on the eye such as pupil centre, limbus centre, fundus or other retinal landmarks can be used to locate the eye. When only one camera is used for

calculating x and y, further dimensions such as z may be found using a second measurement technique; such as optical coherence tomography, interferometery or ultrasound.

In another embodiment IR-diodes are used to measure x and y based on the limbus border and a camera is used to measure the rotation around the visual axis. The other rotations are not considered. Similarly another embodiment uses a pattern projection onto the cornea and two cameras to measure x,y and z position and rotations of this pattern PHI and THETA. Rotation around the z axis is measured using an IR diode array measuring the movement based on markers. This illustrates the breadth of implementation options for this invention which can be based on large number of combinations of measurement techniques to cover the different degrees of freedom.

In order to allow non-rotation-symmetric treatment of the cornea, torsion has to be determined by comparing the current image with the image acquired for definition of the reference. In the preferred embodiment, eye torsion is measured using a cross-correlation technique. Images acquired by Camera 1 are compared with the image acquired for definition of the eye fixed reference system. Here, the greyscale values of an iris segment are cross-correlated with the corresponding segment of the reference iris image (cf. A.H. Clarke, W. Teiwes, and H. Scherer. Video-Oculography - An Alternative Method For Measurement Of Three Dimensional Eye Movements. In: *Oculomotor Control and Cognitive Processes*, eds. R. Schmid and D. Zambarbieri. North Holland: Elsevier Science Publishers, 1991 pp. 431-443). A maximum of the resulting cross-correlation function indicates a matching of the underlying greyscale profiles, i.e. an equal torsion angle. The torsion angle is then determined from the abscissa of the maximum.

In another embodiment, temporary or artificial landmarks such as ink, threads, LASIK flaps, visual patterns generated by the laser during surgery like the shot pattern of a femto-second laser within the stroma or suction rings may be used to calculate torsion or x and y between two measurement or treatment devices. The position of two or more of these landmarks is used to calculate the rotation, PSI.

In another embodiment rotation, PSI can be found by cross-correlation of the fundus image or finding several landmarks on the retina to locate the eye.

The remaining degrees of freedom PHI and THETA are determined by measurement of the geometric distortions of the pupil/limbus border according to the camera position. As three cameras measure these distortions with known angles between their visual axes, size and shape of the pupil/limbus can be compensated. Geometric distortions are small, if the camera is placed close to the visual axis of the eye as the camera observes only the projection of the pupil/limbus. Therefore the above described three camera system provides the possibility to measure distortions with the camera under the best angle.

In the preferred embodiment, the reference image, used to define the 0-torsion angle, is also used for comparison with an image of the eye acquired in a different device or a different step of the diagnosis and treatment process. An iris recognition procedure or security check is applied to check, whether the eyes in those images are identical, i.e. belong to the same person and refer to the same side of the patient (OD/OS).

In the preferred embodiment patient's identity data, the reference image (or several images or measurement data sets depending on the techniques employed) for definition of the eye fixed reference system and the diagnostic or treatment data in eye fixed coordinates are stored together in electronic form. This combination provides the possibility to take full advantage of the invention, because a linkage to the reference eye fixed coordinate system is reached by the coordinate transformations at any step in the diagnosis/ treatment chain. This also holds for the security check or patient eye recognition check. Therefore any two eye related data sets can safely and reliably be compared with each other.

In the preferred embodiment, the reference images undergo a quality check, in which the spatially fixed landmarks are checked to ensure that the image is suitable for further processing ie. Each image at each stage of the process is checked to ensure sufficient quality and features are present on which to base the coordinate system and calculate a transformation.

In the preferred embodiment, the calculation of the correlation performed to find the transformation between eye locations will also return a confidence value. This value gives the level of correlation and reliability of the coordinate transformation.

The present invention outputs the required coordinate transformation and either transforms the diagnostic data or treatment, so that the subsequent diagnostic measurement or surgery is registered to the first.

In the preferred embodiment, a visual comparison check is made of the eye registration, wherein an overlay is used as a marker to facilitate the clinician visually checking the registration against obvious landmarks.

It is important to mention that the coordinate transformation is applicable to any subset of coordinates, if one takes care, that the remaining coordinates are constant in both systems. For example, if the patient fixates a mark, thus ensuring constant inclination angles of the cornea in both devices, then it is sufficient to apply the above methods to the subset of coordinates x, y, z, psi. In this case an accurate laser treatment of non-spherical eye deficiencies (e.g. astigmatism) is already possible.

There exist many more techniques for measurement of the eye co-ordinates, which could be included into this invention:

- Conventional eye tracking based on pupil, outer iris boarder / limbus, or corneal reflections(Purkinje): x, y
- Fringe pattern projection and stereoscopic image processing: x, y, z, PHI, THETA.
- IR diode based limbus or marker tracking: x, y or x, y and z.
- Interferometric measurement: z
- running time of ultrasonic wave: z
- confocal measurement: z
- Cross-correlation, neuronal networks, landmark search, iris recognition, fundus tracking: torsion
- head tracking, slit-lamp, fundus tracking: inclination angles
- geometric distortions, scaling: all coordinates

Claims

We claim:

1. A semi automatic or automatic method for objectively measuring ocular alignment consistently across and within more than one ophthalmic device by performing a comparison process including:
   a. identifying the eye and location of the eye at each device relative to a device-dependent coordinate system;
   b. using spatially defined characteristics of the eye to fix the location of a coordinate system relative to the eye to obtain an eye dependent coordinate system;
   c. using the eye dependent coordinate system to calculate a coordinate transformation between device-dependent coordinate systems and the eye dependent coordinate system.
2. The method of claim 1, further characterized in that the spatially defined characteristics of the eye are fixed naturally occurring landmarks such as the limbus or those naturally occurring in the iris structure, sclera or retina.
3. The method of claim 1, further characterized in that the spatially defined characteristics of the eye are temporarily applied markers or landmarks, or features created during the diagnostic or treatment process such as the LASIK flap or flap cover in LASIK refractive surgery.
4. The method of claim 1, further characterized in that the spatially defined characteristics of the eye are any combination of fixed naturally occurring landmarks and temporarily applied markers or landmarks, or features created during the surgical process, diagnostic or treatment process, which are located relative to the fixed naturally occurring landmarks.
5. The method of claim 1, characterized in that the eye dependent coordinate system and the device-dependent coordinate systems comprise up to 6 spatial degrees of freedom and the pupil diameter.
6. The method of claim 1, characterized in that a transformation is determined between one eye-dependent coordinate system and a second eye-dependent coordinate system or eye-dependent alignment axis, such as the visual axis, line of sight or any other alignment axis.

7. The method of claim 1, characterized in that one or more ophthalmic devices may use one or a combination of measurement techniques to obtain a measurement for one or more degrees of freedom.
8. The method of claim 1, characterized in that the more than one ophthalmic devices can be any combination of ophthalmic devices such as diagnostic and surgical or only diagnostic.
9. The method of claim 1, characterized in that the method is used for the application of identification of the eye (which eye of whom 1:n) and recognition of the eye (is this the correct eye 1:1) either stand-alone or in combination with the coordinate transform and reference system.
10. The method of claim 1, characterized in that the method is used for a technique for the visual comparison of the eye registration, wherein an overlay can be used as a marker to check the registration against visual landmarks.
11. An apparatus for objectively measuring ocular alignment consistently across and within more than one ophthalmic device by performing a comparison process including:
    a. means for identifying the eye and location of the eye at each device relative to a device-dependent coordinate system;
    b. means for using spatially defined characteristics of the eye to fix the location of a coordinate system relative to the eye to obtain an eye dependent coordinate system;
    c. means for using the eye dependent coordinate system to calculate a coordinate transformation between device-dependent coordinate systems and the eye dependent coordinate system.
12. The apparatus of claim 11, further including means for automatically locating suitable landmarks or features for fixing the coordinate system.
13. The apparatus of claim 11, further including means for performing quality checks of an image taken at one device, to ensure that it has sufficient features and landmarks to render it suitable for later comparison and coordinate transformation.
14. The apparatus of claim 11, further including means of calculating and giving a level of confidence on the positional measurement taken.
15. The apparatus of claim 11, further including a means for automatically giving a corrective value for the spatial adjustment of the diagnostic measurement taken or treatment to be applied.

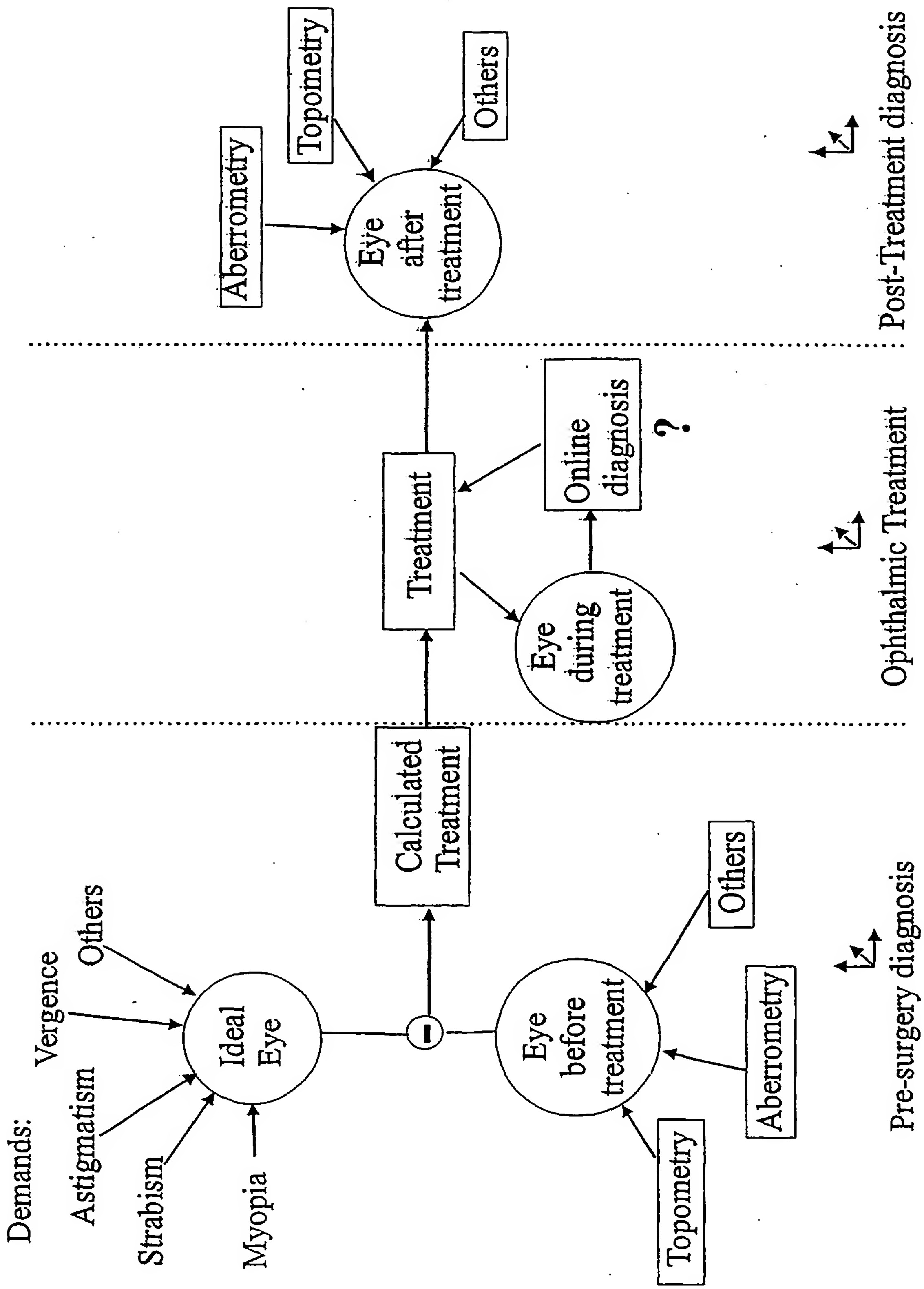

Figure 1. State of the Art Processing Scheme

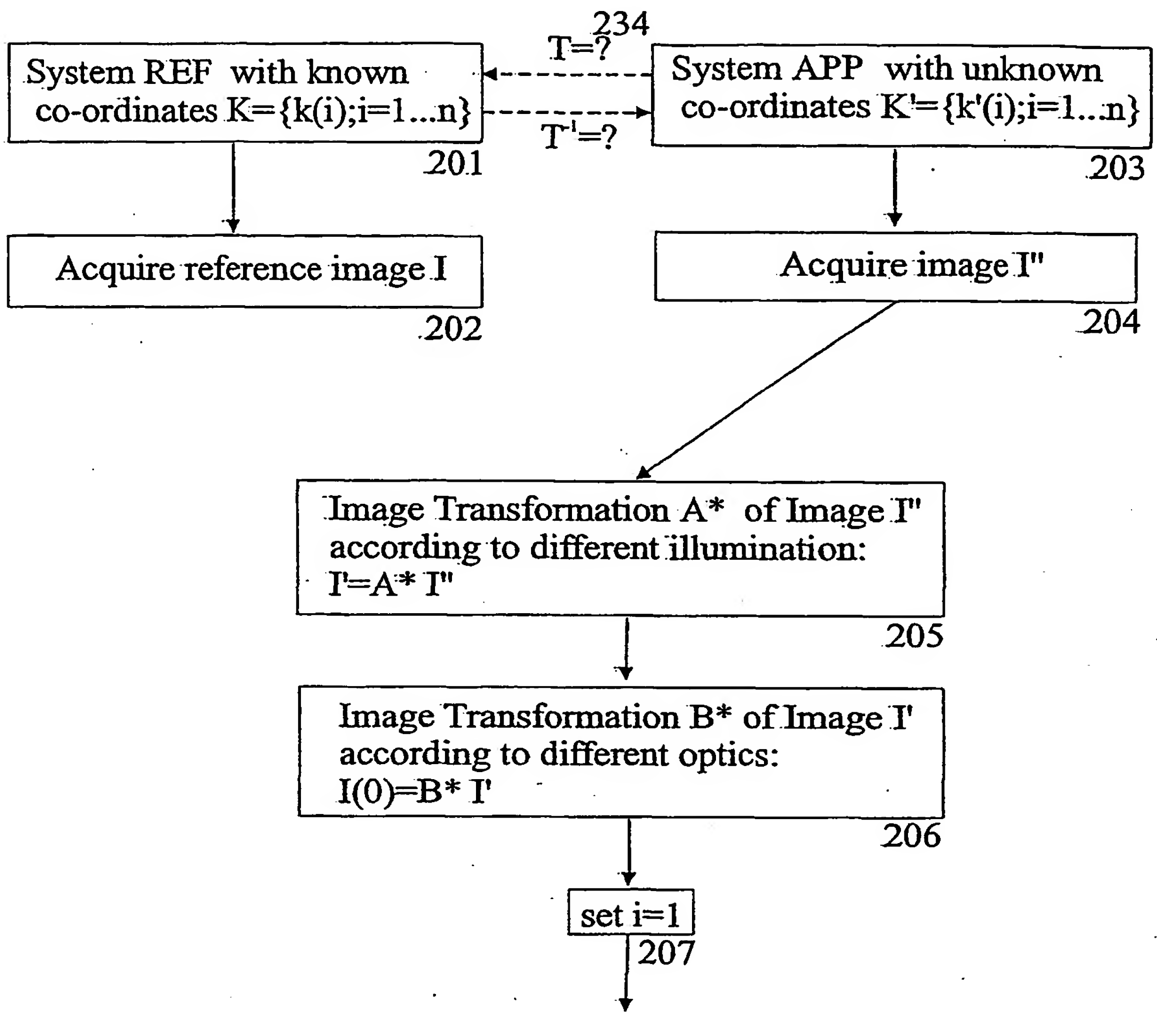

Figure 2. General processing scheme for determination of coordinate transformation from image transformation (upper part)

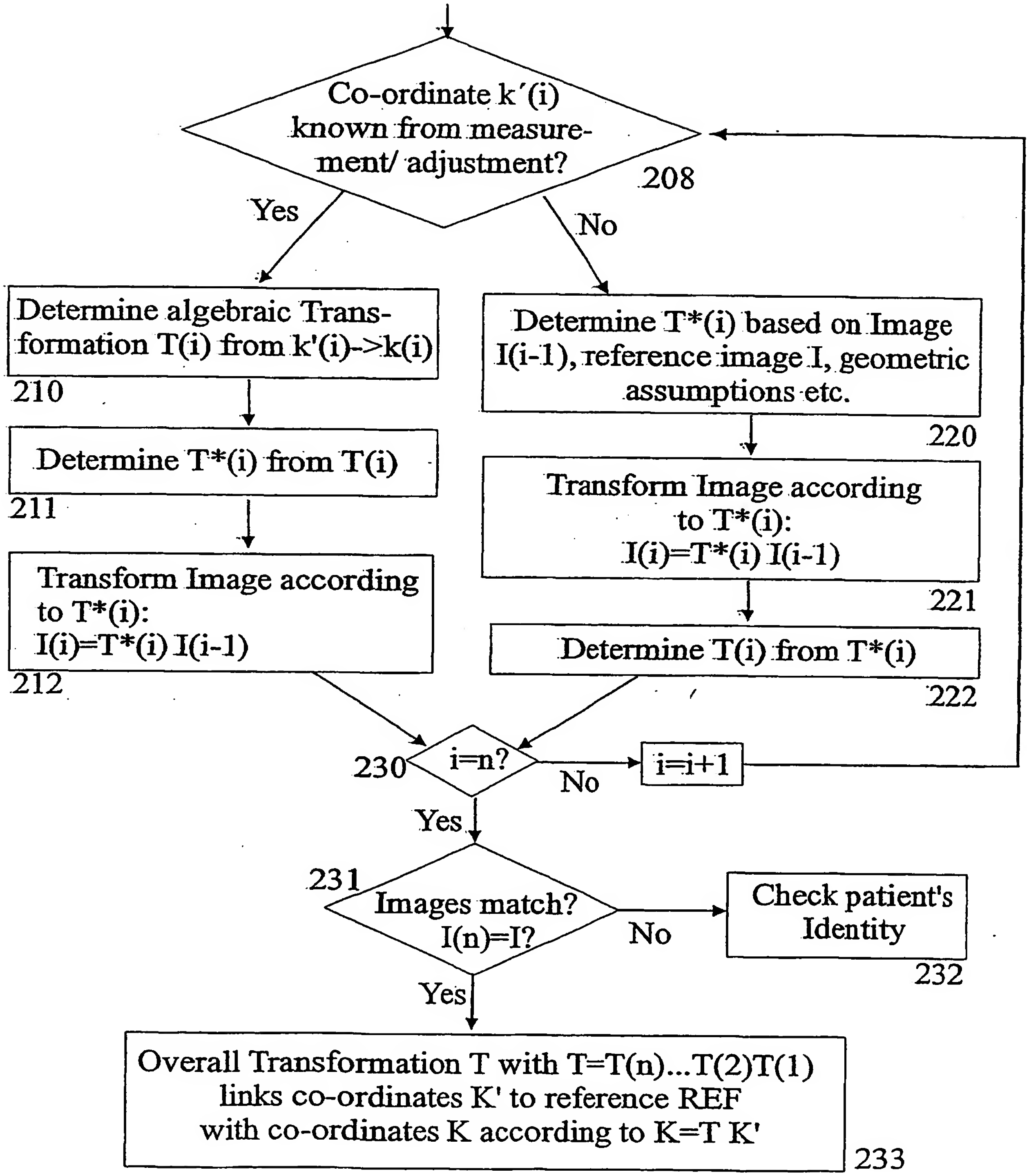

Figure 2. continued (lower part)

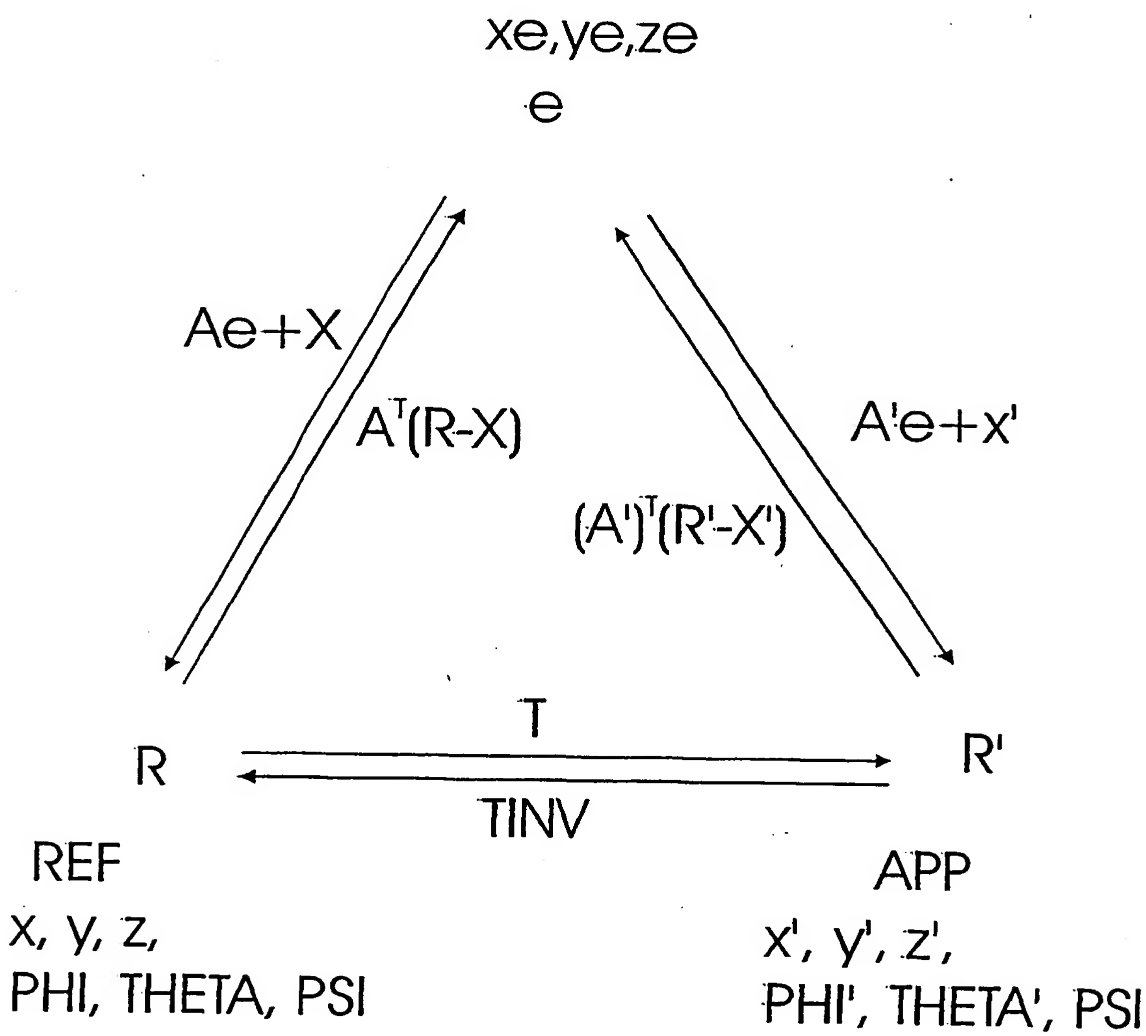

Figure 3. Schematic Transformation Paths

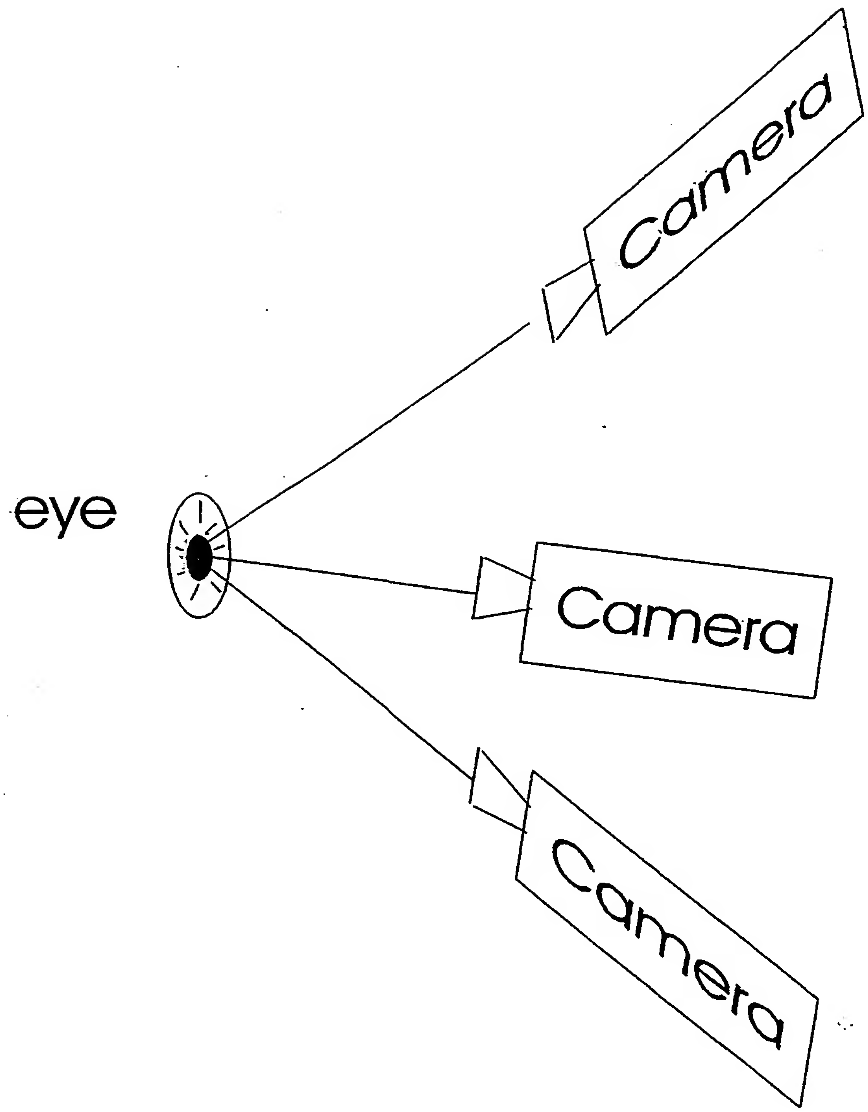

Figure 4. Schematic three camera system

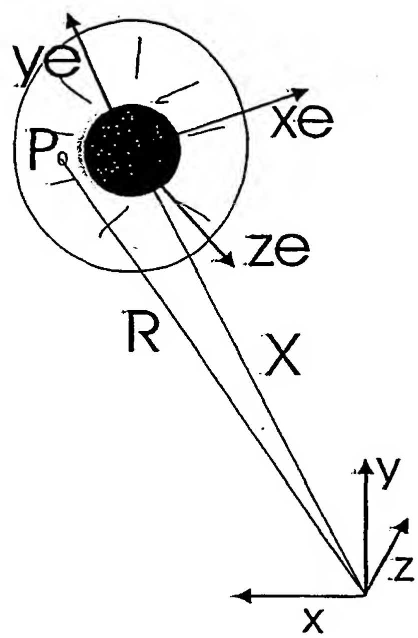

Figure 5. Embedding of schematic eye in co-ordinate system

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR MEASURING OCULAR ALIGNMENT

(57) Abstract: The present invention covers a method and apparatus to measure the position of an eye in up to 6 degrees of freedom, the pupil diameter and the identity of an eye in different diagnosis and treatment instruments and to link and relate the different positions measured at different times and/ or in different instruments to each other. The method used for linking and relating the position measurements to each other is a co-ordinate transformation between the different system co-ordinate systems and the eye co-ordinate system as measured by image processing or other measurement techniques to obtain either single or combined measures of degrees of freedom. In addition to the position of the eye, the identity of the eye under diagnosis or treatment can be measured and recognized in the different instruments and systems. The measurement of the eye position and pupil diameter can also be done with different measurement techniques like standard or non-standard video image analysis from one or several cameras per system, optical coherence tomography, laser interferometry or others.

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INTERNATIONAL SEARCH REPORT

Intl ional Application No
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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 01 28476 A (HOHLA KRISTIAN ;NEUHANN THOMAS (DE); TECHNOLAS GMBH OPHTHALMOLOGIS) 26 April 2001 (2001-04-26) page 3, line 4 -page 5, line 2 page 15, line 2 -page 26, line 13	1-15
A	WO 95 27453 A (CHIRON TECHNOLAS GMBH) 19 October 1995 (1995-10-19) the whole document	1-15

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)			Publication date
WO 0128476	A	26-04-2001	DE	19950791	A1	10-05-2001
			DE	19950790	A1	21-06-2001
			DE	10014479	A1	04-10-2001
			AU	1514801	A	30-04-2001
			WO	0128476	A1	26-04-2001
			AU	1026401	A	30-04-2001
			WO	0128410	A1	26-04-2001
WO 9527453	A	19-10-1995	US	5645550	A	08-07-1997
			AU	2216095	A	30-10-1995
			AU	697055	B2	24-09-1998
			AU	2305395	A	30-10-1995
			CA	2187373	A1	19-10-1995
			WO	9527453	A1	19-10-1995
			WO	9527454	A1	19-10-1995
			EP	0754019	A1	22-01-1997
			JP	10501707	T	17-02-1998
			US	5620436	A	15-04-1997